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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,265

04/04/2005

Richard Andrew Snell

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8824

23859 7590 04/12/2007  
NEEDLE & ROSENBERG, P.C.  
SUITE 1000  
999 PEACHTREE STREET  
ATLANTA, GA 30309-3915

EXAMINER

HALL, DEANNA K

ART UNIT

PAPER NUMBER

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/522,265	SNELL ET AL.	
	Examiner	Art Unit	
	Deanna K. Hall	3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on January 25, 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>April 4, 2005</u>   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement (IDS) submitted on April 4, 2005 is in compliance with the provisions of 37 CFR 1.97(b). Accordingly, the IDS is being considered by the Examiner.
2. However, the information disclosure statement filed April 4, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Therefore FR 2,292,487 has been placed in the application file, but the information referred to therein has not been considered.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 4-5, 7-11 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al. (US 5,147,323) ("Haber").** Haber discloses: a two-part syringe 2 comprising two chambers 6,8 each with an associated plunger 42, 44 interlinked so as selectively to prevent movement of one of said plungers in its respective chamber dependent upon the position of the other plunger C4 L19-44. The

Art Unit: 3767

interlinking of Haber's invention is configured to be capable of reconstituting and injecting a lyophilized drug **C1 L33- C2 L12**. Haber further discloses a cam shuttle **14** constrained to move within a void extending perpendicularly to the plungers **C4 L19-44**. The two chambers of Haber can be placed selectively in fluid communication with one another **C1 L33-39; 10, 70**. Haber further discloses a communicating conduit **50** and a seal **36** associated with one or both of the chambers **C3 L42-47**. The communicating conduit **50** comprising one or two needles **52, 53** for breaching said seals **C3 L42-47** and a tortuous or complex fluid path **C3 L42-60**. Said communicating conduit is provided on a support member **68** which is slidable so as to bring the conduit into and out of engagement with the chambers **C3 L45-60; C2 L30-34**.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Pizzino (US 4,610,666).** Haber shows as discussed above. An object of Haber's invention is to drive each of the pistons of the multiple cartridge syringe one-at-a-time **Haber C2 L13-14**. Pizzino, in the analogous art, teaches a cam means associated with the plungers **C4 L38-60**. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify

the device of Haber with the cam means as taught by Pizzino for dispensing the liquids one at a time in predetermined sequence **Pizzino C2 L63-66**.

7. **Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Pizzino (US 4,610,666).** Haber shows as discussed above. An object of Haber's invention is to allow a user to select the amounts and proportions of two types of insulin delivered with a single injection **C1 L33-40**. Pizzino, in the analogous art, teaches the plungers having a different appearance **C3 L62- C4 L 27**. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Haber with the plungers of different appearances as taught by Pizzino since having distinguishable plungers will ensure that the user selects the amount and proportion of the correct type of insulin to be delivered **Haber C1 L33-40**.

8. **Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber/Pizzino further in view of Pawelka et al. (US 5,505,704) ("Pawelka").** The Haber/Pizzino combination shows as discussed above. Haber even discloses an end cap 68 being permanently mounted to the housing with the end cap comprising the support plate 50 with its hollow spikes 52, 53 **C3 L 42-60**. Pawelka, in the analogous art, teaches the communicating conduit provided on a separate, plastic support member which is slidable towards or away from the chambers **C5 L17-46; Figs. 3-5**. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Haber with the separate support member as taught by Pawelka for allowing the syringe a reuseable design **Haber C2 L30-34**.

Art Unit: 3767

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 8:00am-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER



Deanna K. Hall  
Examiner  
AU 3767

dkh